



Vaxart Announces Selection of its Oral COVID-19 Vaccine Lead Candidate

May 20, 2020

KindredBio Selected as Second Contract Manufacturing Organization

GMP Production for Phase 1 Study Initiated

SOUTH SAN FRANCISCO, Calif., May 20, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc. ("Vaxart" or the "Company") (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced that it has selected its lead COVID-19 vaccine candidate and has contracted with KindredBio to manufacture bulk vaccine under cGMP to complement the manufacturing capacity of partner Emergent BioSolutions.

"All our COVID-19 vaccine constructs were highly immunogenic in preclinical testing, and we are taking the candidate forward that is expected to generate the broadest immune response in humans," said Sean Tucker, Ph.D., chief scientific officer of Vaxart. "In a phase 2 efficacy study that was recently published in the *Lancet Infectious Diseases*, we have demonstrated that our oral H1 flu tablet vaccine protected against influenza infection after just one dose. Based on these results, we believe our vaccines are ideal to protect against mucosal respiratory viruses such as SARS-CoV-2, the virus that causes COVID-19."

In January 2020, Vaxart initiated a program to develop a COVID-19 vaccine based on its VAAST™ oral vaccines platform. The Company evaluated multiple vaccine candidates in its preclinical models and has chosen the lead candidate for cGMP manufacturing and clinical testing based on the magnitude and the breadth of the immune response. Vaxart has contracted with Emergent BioSolutions ("Emergent") and Kindred Biosciences, Inc. ("KindredBio") to produce bulk vaccine under cGMP for upcoming clinical trials. The vaccine tablets will be manufactured at Vaxart.

"We are very pleased to have an experienced partner such as KindredBio to help us meet global demand for our COVID-19 vaccine," said Wouter Latour, MD, chief executive officer of Vaxart. "The program with Emergent BioSolutions is progressing very well, and we expect KindredBio will add additional capacity to help produce bulk vaccine. An important benefit of our platform is that our vaccines are produced in tablet form and we don't need the sterile fill and finish that is required for the production of injectable vaccines. Manufacturing of our COVID-19 vaccine is on track to start its first phase 1 study in the second half of this year, possibly as early as the summer."

About Vaxart

Vaxart is a clinical-stage biotechnology company primarily focused on developing oral recombinant protein vaccines based on its proprietary oral vaccine platform. Vaxart's vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may also be useful for the treatment of chronic viral infections and cancer. Vaxart's vaccines are administered using a convenient room temperature-stable tablet, rather than by injection. Vaxart believes that tablet vaccines are easier to distribute and administer than injectable vaccines and have the potential to significantly increase vaccination rates. Vaxart's development programs include oral tablet vaccines that are designed to protect against coronavirus, norovirus, seasonal influenza and respiratory syncytial virus ("RSV"), as well as a therapeutic vaccine for human papillomavirus ("HPV"). For more information, please visit www.vaxart.com.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Vaxart's strategy, prospects, plans and objectives, results from pre-clinical and clinical trials, commercialization agreements and licenses, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "should," "believe," "could," "potential," "will," "expected," "plan" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to Vaxart's ability to develop and commercialize its product candidates and clinical results and trial data (including plans with respect to the COVID-19 vaccine product candidates); expectations relating to Vaxart's relationship with Emergent and KindredBio, including their ability to produce bulk cGMP vaccine and the timing and capacity thereof; Vaxart's ability to manufacture vaccine tablets; the expected timing of the first phase 1 study; expectations regarding Vaxart's lead COVID-19 vaccine candidate; and Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Vaxart makes, including uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; decisions by regulatory authorities impacting labeling, manufacturing processes, and safety that could affect the availability or commercial potential of any product candidate, including the possibility that Vaxart's product candidates may not be approved by the FDA or non-U.S. regulatory authorities; that, even if approved by the FDA or non-U.S. regulatory authorities, Vaxart's product candidates may not achieve broad market acceptance; that a Vaxart collaborator may not attain development and commercial milestones; that Vaxart may experience manufacturing issues and delays due to events within, or outside of, Vaxart's control, including the recent outbreak of COVID-19; that Vaxart may not be able to obtain, maintain and enforce necessary patent and other intellectual property protection; that Vaxart's capital resources may be inadequate; Vaxart's ability to obtain sufficient capital to fund its operations on terms acceptable to Vaxart, if at all; the impact of government healthcare proposals and policies; competitive factors; and other risks described in the "Risk Factors" sections of Vaxart's Quarterly and Annual Reports filed with the SEC. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

Contact

Brant Biehn
Vaxart Inc
650 550 3500

IR@vaxart.com



Source: Vaxart, Inc.